

## **REMARKS/ARGUMENTS**

### **I. STATUS OF THE APPLICATION**

Claims 237-289 are presently pending and stand rejected. In the July 31, 2008 amendment and response to the February 1, 2008 Office Action, Claims 291-299 were newly added. These claims have been renumbered 281-289 by the Examiner. By way of this response, four (4) claims have been amended. Support for the amendments can be found at least in paragraphs [0071]-[0075], [0125], [0107], [0118], [0123], [0162]-[0194], [0230]-[0233], and [0556]-[0601], and Example I of the published application U.S. Patent Application Ser. No. 2005/0004171. Applicant respectfully submits that no new matter has been added by way of this amendment. No fees are believed due.

### **II. THE CLAIMS ARE ENABLED UNDER 35 U.S.C. § 112, FIRST PARAGRAPH, AND THE REJECTION SHOULD BE WITHDRAWN**

The rejection under 35 U.S.C. § 112, first paragraph, of Claims 237-280 stands maintained as allegedly failing to comply with the enablement requirement. In particular, the Office Action provided that (1) “there was no description of what [the] ‘range’ [of the disintegrant] would be for the instant invention”; (2) “no relationship between the 12 mg croscarmellose sodium can be extrapolated to ranges of all disintegrant material with completely different property, molecular weight and efficacy”; and (3) “there is no evidence in the record that a composition meeting the ratio requirement without using bicarbonate as the buffering agent or meeting the range requirement of the currently amended scope.”

The scope of enablement must only bear a “reasonable correlation” to the scope of the claims. M.P.E.P. § 2164.08. Applicants respectfully submits that the specification provides a scope of enablement reasonably correlated with the scope of the currently amended claims. The Examiner states that “the specification provides examples containing 12 mg disintegrant or 66 mg disintegrant while there was no description of what ‘range’ would be for the instant invention.” Applicants submit that the specification also provides examples of compositions having 27.27 mg and 45.45 mg of disintegrant. *See* paragraphs [0571]-[0574], of the published application (U.S. Patent Application Ser. No. 2004/0004171). Therefore, the specification describes examples spanning 12 mg, 27.27 mg, 45.45 mg and 66 mg of disintegrant. Based on these examples, the claimed ranges are fully enabled for one of ordinary skill in the art.

The Office Action further alleged that “no relationship between the 12 mg croscarmellose sodium can be extrapolated to ranges of all disintegrant material with completely different property, molecular weight and efficacy.” Applicant respectfully submits that the specification discloses examples of disintegrants, other than croscarmellose sodium; for example, pregelatinized starch. *See* paragraphs [0573] and [0574] of the published application. Further, the Examiner admits that “the incorporation of disintegrant is conventional modification in the pharmaceutical composition art and can be derived by one having ordinary skill. . .” *See* page 2 of the November 10, 2008 Office Action. A skilled artisan would be able to derive an amount within the claimed ranges for other known disintegrants based on the type and efficacy of the disintegrant.

Lastly, the Office Action alleged that there is no evidence of record that buffering agents, other than sodium bicarbonate, is enabled. Without admitting or conceding in any manner that the rejected claims fail to comply with the enablement requirement under 35 U.S.C. § 112, first paragraph, and solely to expedite the prosecution of the present application, Claims 237 and 254 have been amended to modify the group of buffering agents to those having similar solubility and pK as sodium bicarbonate. In addition, the specification provides numerous examples on how to calculate the amount of one or more buffering agents with a proton pump inhibitor (“PPI”) to prevent gastric acid degradation of the PPI. *See* paragraphs [0494]-[0540].

In view of the present amendments and the foregoing arguments, Applicants respectfully request withdrawal of the rejection of Claims 237-280 under 35 U.S.C. § 112, first paragraph.

**III. THE CLAIMS ARE NOT ANTICIPATED UNDER 35 U.S.C. § 102(f) OR (g) BY THE CITED PRIOR ART REFERENCES, AND THE REJECTION SHOULD BE WITHDRAWN**

The rejection of Claims 237-280 under 35 U.S.C. § 102(f) or (g) stands maintained as allegedly being anticipated by U.S. Patent Application Nos. 2005/0037030 (“Hall et al.”) or 2005/0266071 (Olmstead et al.). Applicant respectfully traverses the rejection. Applicant incorporates by reference the Response dated July 31, 2008 to the February 1, 2008 Office Action. The instant application is a continuation of U.S. patent application Ser. No. 10/722,184, filed on November 25, 2003, which is a continuation of U.S. patent application Ser. No. 10/054,350, filed on Jan. 19, 2002, now U.S. Pat. No. 6,699,885, which is a continuation-in-part of U.S. patent application Ser. No. 09/901,942, filed on Jul. 9, 2001, now U.S. Pat. No.

6,645,988, which is a continuation-in-part of U.S. patent application Ser. No 09/481,207, filed on Jan. 11, 2000, now U.S. Pat. No. 6,489,346, which is a continuation-in-part of U.S. patent application Ser. No 09/183,422, filed on Oct. 30, 1998, now abandoned, which is a continuation-in-part of U.S. patent application Ser. No. 08/680,376, filed on Jul. 15, 1996, now U.S. Pat. No. 5,840,737, which claims priority to U.S. Provisional Application Ser. No. 60/009,608, filed on Jan. 4, 1996.

Without admitting or conceding that U.S. provisional application Ser. No. 60/009,608., filed on January 4, 1996, does not provide support for the disintegrant – croscarmellose sodium – Applicant respectfully submits that there is support for croscarmellose sodium in the most recent related application. The disintegrant, croscarmellose sodium, is supported at least in U.S. patent application Ser. No. 10/722,184, filed on November 25, 2003, in paragraphs [0121], [0123], [0127], [0148]-[0169], and [0547]-[0569] of the published application (U.S. Patent Application Ser. No. 2004/0171646). Furthermore, Applicant does not waive its right to claim an earlier priority date. As such, this application claims priority through its related application(s) at least before the publication and filing dates of both Hall et al. and Olmstead et al. Accordingly, neither Hall et al. or Olmstead et al. is prior art under 35 U.S.C. § 102(f) or (g).

For the foregoing reasons, Applicant respectfully request withdrawal of the rejection of Claims 237-280 under 35 U.S.C. § 102(f) or (g).

#### **IV. OBVIOUSNESS-TYPE DOUBLE PATENTING**

Claims 237-289 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-17 of U.S. 6,489,364 in view of Jung et al. (CA 128:261816); claims 237-280 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18-56 of U.S. 6,489,364 or claims 1-51 of U.S. 6,699,885 or claims 24-25, 32-36, 77-88, 90-100, and 103-110 of copending U.S. Patent Appl. Ser. No. 10/641,732, as described in the Office Action. Applicant understands that the Examiner was referring to U.S. 6,489,346 instead of U.S. 6,489,364. Without admitting or conceding in any manner that the rejected claims are unpatentable over the above-referenced issued in view of Jung et al., and solely to expedite the prosecution of the present application, Applicant will consider submitting a terminal disclaimer upon the indication of allowable subject matter.

May 8, 2009

## CONCLUSION

For at least the foregoing reasons, it is respectfully submitted that the pending claims are in condition for allowance. Early and favorable consideration is respectfully requested, and the Examiner is encouraged to contact the undersigned with any questions or to otherwise expedite prosecution. Further, none of Applicant's amendments or cancellations are to be construed as dedicating any such subject matter to the public, and Applicant reserves all rights to pursue any such subject matter in this or a related patent application.

Kindly contact the undersigned with any questions or to otherwise expedite prosecution.

Respectfully submitted,

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